

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Serial No.:	10/643,181	Confirmation No.:	3632
Filed:	August 18, 2003		
Group Art Unit:	3732		
Examiner:	Melba N. Bumgarner		
Applicant:	Farrokh Farzin-Nia et al.		
Title:	AESTHETIC SELF-LIGATING ORTHODONTIC BRACKET		
Attorney Docket:	ORM-230US		

Cincinnati, Ohio 45202

June 26, 2006

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**AFFIDAVIT UNDER RULE 131**

We, Farrokh Farzin-Nia and Albert Ruiz-Vela (the inventors), being duly cautioned and sworn, submit this Affidavit in response to the Office Action dated April 24, 2006, and state:

That we are the inventors of the invention entitled "AESTHETIC SELF-LIGATING ORTHODONTIC BRACKET" described and claimed in the application for Letters Patent of the United States, Serial No. 10/643,181, filed August 18, 2003 ('181 application);

That this is an Affidavit under the provisions of Rule 131 and the rules of practice for the United States Patent Office in support of said '181 application;

That the invention described and claimed in the '181 application was conceived prior to June 21, 2002, which represents the earliest possible effective filing date of U.S. Patent Application Publication No. 2004/0072119 filed in the name of Voudouris;

That, as evidence of the conception of the invention described and claimed in the '181 application, attached and incorporated into this Affidavit as Exhibit A are photocopies of an original written invention disclosure, including original drawings, bearing a date (now masked) made by one or both of the undersigned inventors prior to June 21, 2002, bearing a date prior to June 21, 2002, but with said date now masked;

That, as further evidence of the conception of the invention described and claimed in the '181 application, attached and incorporated into this Affidavit as Exhibit B are photocopies of images of a scaled model of an orthodontic bracket made under the direction of one or both of the undersigned inventors before June 21, 2002;

That the attached Exhibits A and B include a detailed description of a self-ligating orthodontic bracket, which clearly demonstrates that such self-ligating orthodontic bracket embodies the elements claimed in at least the independent claim of the '181 application, and which was conceived prior to the effective date of Voudouris;

That the conception of the invention claimed in at least pending independent claim 28 of the '181 application is fully supported by the attached Exhibits A and B, and that all information included in the Exhibit having been created in the United States by one or both of the undersigned inventors before June 21, 2002;

That the Exhibit demonstrates as follows:

That a self-ligating orthodontic bracket was conceived before June 21, 2002;

That the self-ligating orthodontic bracket comprised a metallic self-ligating assembly including an archwire slot and a ligating member movable between an open position in which an archwire is insertable into said archwire slot and a closed position in which the archwire is retained in said archwire slot; and a bracket body configured to be mounted to a tooth and carrying said metallic self-ligating assembly, said bracket body comprising a non-metallic material.  
as called for in the pending independent claim in the '181 application;

That the '181 application claims the benefit of provisional application Serial No. 60/404,345 filed on August 19, 2002, which represents the effective filing date of the '181 application;

That the undersigned inventors were diligent from prior to the filing date of June 21, 2002 of U.S. Patent Application Publication No. 2004/0072119 to the August 19, 2002 filing date of provisional application Serial No. 60/404,345. Specifically, the undersigned inventors can account for the entire period during which reasonable diligence is required with affirmative acts and acceptable excuses. During this period, outside counsel for the Assignee acted within

the United States with reasonable diligence on the application. Specifically, the attached Exhibit A was prepared by the inventors and forwarded to outside counsel for the Assignee on June 15, 2002. The attached Exhibit B includes photographs of a scale model constructed before June 15, 2002. Outside counsel for the Assignee was diligent in drafting a specification, which was approved by the inventors and filed as provisional application Serial No. 60/404,345 on August 19, 2002. In particular, outside counsel for the Assignee had a reasonable backlog of unrelated cases taken up in chronological order and carried out expeditiously;

Therefore, in summary, the Declaration and attached Exhibits constitute a showing of facts, in character and weight, that establish conception of the invention prior to the filing date of U.S. Patent Application Publication No. 2004/0072119 for a self-ligating orthodontic bracket that is the subject of and is claimed in Application Serial No. 10/643,181, all the acts of which occurred in the United States BEFORE June 21, 2002, and thus precede the earliest possible effective filing date of U.S. Patent Application Publication No. 2004/0072119, and that the inventors and counsel for the inventors exhibited diligence from prior to the earliest possible effective filing date of June 21, 2002 of U.S. Patent Application Publication No. 2004/0072119 to the August 19, 2002 filing date of provisional application Serial No. 60/404,345.

Further affiants sayeth naught.

By *Farrokh Farzin-Nia*  
Farrokh Farzin-Nia

Date 7/12/06

STATE OF CALIFORNIA )  
COUNTY OF Los Angeles )

2006. Sworn to and subscribed in my presence this 12<sup>th</sup> day of July.

(SEAL)

*Martha Lomeli*  
Notary Public



By Albert Ruiz-Vela  
Albert Ruiz-Vela

Date 7-13-06

STATE OF CALIFORNIA )  
COUNTY OF Los Angeles )

2006. Sworn to and subscribed in my presence this 13<sup>th</sup> day of July.

(SEAL)

Martha Lomeli  
Notary Public



EXHIBIT A

Don Frei, Esq.  
Wood, Heron & Evans  
2700 Carew Tower  
Cincinnati, Ohio 45202-2917

Re.: "Disclosure on Aesthetic Self Ligating Bracket"

Dear Don:

Enclosed, please find a disclosure on Aesthetic Self-Ligating Bracket. The bracket is specifically designed to compliment Damon Bracket line. However, the application can be expanded to other techniques as well.

Inventors:

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Inglewood, CA 90302

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5737 Peridot Ave.  
Alta Loma, CA 91701

Sincerely yours,

  
Farrokh Farzin-Nia

## Disclosure Statement:

### **Introduction and Definitions:**

Use of self-ligating brackets is gaining momentum in orthodontic market. There are two approaches in self-ligating brackets. One approach is "Passive Self Ligation" in which the labial (buccal) side of the slot is closed via a mechanism forming a tube like channel in the slot. The wire can slide easily in the slot without being held down by a ligation system.

In the alternative approach the mechanism that closes the bracket slot also acts as an active ligation system that would force the wire to the bottom of the bracket slot.

Each approach is favored by a different group of clinicians depending on their particular treatment philosophy and clinical technique.

Dr. Damon has developed a bracket and a treatment system that has been received in the market favorably. The system developed by Dr. Damon uses a passive self-ligating bracket that is patented under his name. In this bracket a gate moves slidingly in the occlusal / gingival direction and closes the opening of the slot after the wire is placed in the bracket slot.

One of the problems associated with self-ligating bracket is their size and aesthetics. Self-ligating brackets are generally larger than the regular brackets because they have to include a functional mechanical system to the bracket assembly. Also, the functional assembly nature of the self ligating brackets necessitate the use of metallic materials because of their strength combined with their ductility and toughness relative to plastics or ceramics.

Aesthetics remain a very desirable characteristic for the orthodontic appliances. In the current application we are attempting to disclose a self-ligating bracket with improved aesthetics by using a combination of materials in the design of the bracket.

### **New Concept:**

An orthodontic bracket consists of several different functional segments that are integrally combined to form the bracket assembly. Generally, self-ligating brackets consist of all the segments of the regular bracket plus an added feature that is used for containing the wire in the bracket slot (ligation system). This feature has moving parts, unlike the regular orthodontic brackets. In the current design of this invention the ligation system is made of metallic materials and is contained by insert molding in a plastic (composite) bracket body. This combination provides reliable functional performance from the metallic material in the ligation system of the bracket and the aesthetics of the plastic material for the body of the bracket rendering an overall pleasing aesthetic appearance in the bracket assembly.

The main features of the new design are as follows:

1. Self-ligation system and the slot assembly (SLSA) of the bracket are made of the metallic materials.
2. The bracket body is made of non-metallic materials. Primarily plastic or composite.
3. The SLSA is contained within the non-metallic bracket material.
4. The bracket assembly is manufactured by insert molding.

5. The ligation system consists of a "slide" that slides occlusal gingivally for closing the bracket slot opening after the insertion of the archwire into the bracket slot.
6. The slide in the ligation system is contained on its mesial – distal sides within two grooves that are located on the mesial and distal sides of the ligation system body above the slot opening. Same as the Damon bracket.
7. The slide, when closed covers the top of the slot and butts against the slot wall at the opposite side of the slot to where the slide assembly is located.
8. The slide has an opening for receiving a tool and pressing the spring in the lingual direction while sliding the slide away from the slot to open the ligation system.
9. The tool is a one piece metallic instrument that consists of a nib the can be inserted into the opening at the top of the slide, a shoulder that can limit how far the nib can penetrate into the slot, and handle for holding the tool.
10. The end of the tool can be bent for improved ergonomics and for easier access to the opening.
11. The slide is held in place with spring that controls the location of the slide in both open and closed positions. When in the closed position the spring snaps into the opening in the slide and locks the position of the slide. During the opening of the slide the tool removes the spring out of the slide opening and allows the tool to slide the slide to the open direction.
12. The other end of the spring is held within the body of the ligation mechanism in the slide side of the slot, and is extended, through a groove in the back of the slide, into the slide opening.
13. The side of the spring in the ligation system that is held within the ligation system acts as a stop when the slide is in the open position.
14. The spring can be made from stainless steel or Ni/Ti type (superelastic) materials.
- 15.

1. An aesthetically pleasing orthodontic bracket consisting of a metallic ligation system combined with a non-metallic aesthetically pleasing material.
2. An orthodontic bracket ligation system which includes a housing that would accommodate a slide, a slot for receiving the orthodontic archwire, the slide that would slidingly cover the slot and secure the archwire within the slot.
3. A spring made for determining the location of the slide in the open and closed positions, where the body of the spring, independent of the spring action, provides a stop in the open

position, and where the spring action provide a lock in the position of the slide in the closed position. Force of the spring is not relevant to the performance of the slide.

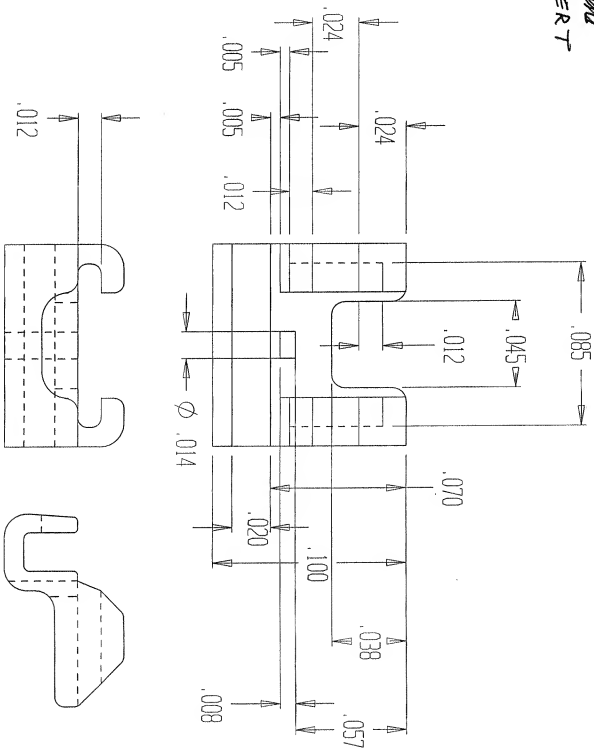
4. A ligation mechanism consisting of a slide, and a housing where the movement of the slide in the open an closed positions are limited with a spring, where the spring can provide stop in the location of the slide in the open position through a groove that is located lingually on the slide, and provide a stop in the closed position through an opening in the opposite side of the slide.
5. A tool that can be engaged in the opening of the slide for opening the slide. Various designs on the slide may be made to assist in engaging the tool in the opening of the slot.

#### **Other Details:**

1. The slot section of the ligation system assembly is encapsulated within the bracket body.
2. The bracket body is made of filled polycarbonate composites, Acrylic based thermoplastics, Acrylic thermosets, structural plastics, and ceramics.
3. The spring material can be stainless steels, specifically 17-7 PH material, Ti alloys or Ni/Ti materials.
4. The ligation system is preferably made of stainless steel, specifically type 17-4.

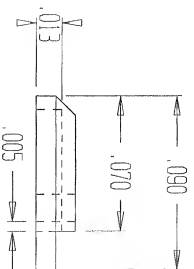
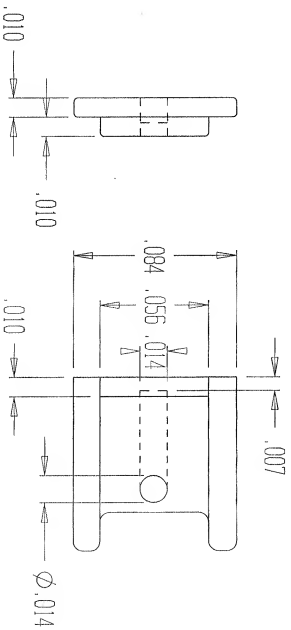


# AESTHETIC DAMON BRACKET BUILDING INSERT

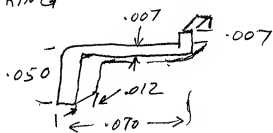


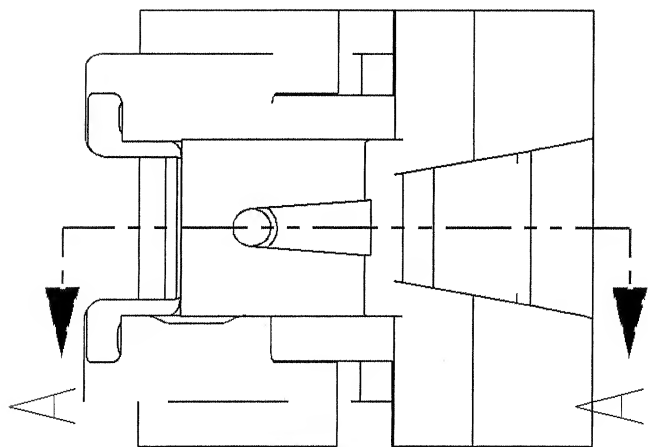
# SLIDE

Farrokh Forzin-Nia  
 Damon, Aesthetic Bracket Slide  
 Material 17-4 PH, RC 42 min.  
 Tolerances:  $\pm 0.0005$  on all Dimensions



SPRING





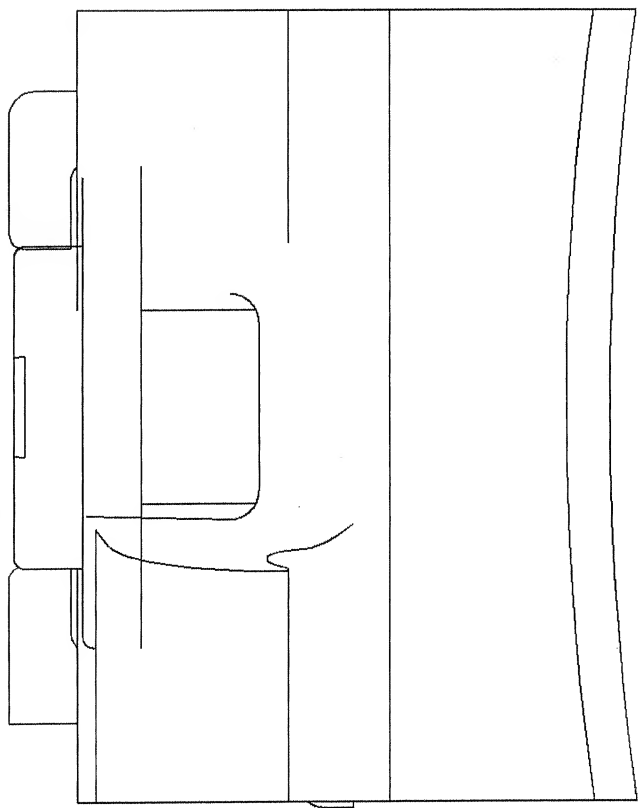


EXHIBIT B

